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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|-----------------|---------------------------------|----------------------|-----------------------|-------------------------|--|--|
| 10/766,502 | 01/28/2004 | Maryse Lafouasse | P06312US01 - PHI 1367 | 3477 | | |
| 27142 | 7590 02/17/2005 | | EXAMINER | | | |
| , | OORHEES & SEASE, EER HI-BRED | KRUSE, DAVID H | | | | |
| | AVENUE, SUITE 3200 | ART UNIT | PAPER NUMBER | | | |
| DES MOINE | S, IA 50309-2721 | 1638 | | | | |
| | | | | DATE MAILED: 02/17/2005 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Applicati | on No. | Applicant(s) | | | | |
|---|--|-----------|--|-------------------|--------|--|--|--|
| Office Action Summany | | 10/766,5 |)2 | LAFOUASSE, MARYSE | | | | |
| | Office Action Summary | Examine | | Art Unit | | | | |
| | | David H K | | 1638 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM | | | | | | | | |
| THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | |
| Status | | | | | | | | |
| 1) | 1) Responsive to communication(s) filed on | | | | | | | |
| 2a) <u></u> ☐ |)☐ This action is FINAL . 2b)⊠ This action is non-final. | | | | | | | |
| 3)[| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | | |
| 4)⊠ Claim(s) <u>1-10</u> is/are pending in the application. | | | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| | 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) <u>1-10</u> is/are rejected. | | | | | | | |
| | | | | | | | | |
| | Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | | |
| Application Papers | | | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| | | | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | | |
| | e of References Cited (P1O-892) e of Draftsperson's Patent Drawing Review (PTO-9 | 148) | 4) Interview Summary (Paper No(s)/Mail Da | | | | | |
| 3) 🛛 Inform | nation Disclosure Statement(s) (PTO-1449 or PTO/ r No(s)/Mail Date <u>1/28/2004</u> . | | 5) Notice of Informal Pa | |)-152) | | | |

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 28 January 2004 has been considered, a signed copy is attached hereto.

Claim Objections

2. Claim 1 is objected to because of the following informalities: Claim 1 of the originally filed application did not have a claim number designation. Applicant should acknowledge this form error in response to this Office action and include the appropriate claim number in any subsequent response. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
- 4. Claims 2 and 3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite because claim 2 recites "the F1 hybrid maize seed of claim 1", which lacks proper antecedent basis in claim 1. Claim 3 is also indefinite because it is dependent upon claim 2.
- 5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 6. Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter,

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims progeny of inbred maize line PH0GC.

Applicant describes inbred maize line PH0GC in terms of phenotypic and morphological traits in Table 1, pages 18-20 of the specification, and a single double hybrid progeny produced from a cross between the deposited PH0GC inbred maize line and PH16K further crossed with a hybrid produced by crossing PHK05 with PH854 in Table 4, page 39 of the specification.

Applicant does not describe the genus of progeny produced by crossing inbred maize line PH0GC with other maize plants.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). The instant claims are directed to a product wherein only a partial structure is described by a deposit of representative seed. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to

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satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or artrecognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

7. Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims progeny of inbred maize line PH0GC.

Applicant teaches inbred maize line PH0GC in terms of phenotypic and morphological traits in Table 1, pages 18-20 of the specification, and a single double hybrid progeny produced from a cross between the deposited PH0GC inbred maize line and PH16K further crossed with a hybrid produced by crossing PHK05 with PH854 in Table 4, page 39 of the specification.

Applicant does not teach how to make and use the genus of progeny produced by crossing inbred maize line PH0GC with other maize plants.

Applicant only teaches a single double hybrid maize plant having inbred maize line PH0GC as one of its parents. The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). The nature of the art at the time of Applicant's invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that "Even if an inbred in hybrid combination has excellent yield (a desired characteristic), it may not be useful because it fails to have acceptable parental traits such as seed yield, seed size, pollen production, good silks, plant height, etc." (Carlone,

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U.S. Patent 5,763,755, column 2, lines 11-14). The art teaches that based on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be found in a large F₂ or S₀ population and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebart, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3). The art also teaches that the number of genes affecting the trait of primary economic importance in maize, grain yield, has been estimated to be in the range of 10-1000 and that inbred lines which are used as parents for breeding crosses differ in the number and combination of these genes (Segebart, U.S. Patent 5,367,109, column 2, lines 60-64). Segebart ('109) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use their skills, experience and intuitive ability to select inbreds having the necessary qualities (column 4, 1st and 2nd paragraphs). Hence, given the fact that one of skill in the art cannot reasonably predict the number of genes that affect the trait of grain yield of the parental inbred lines of a inbred maize plant, it is unclear how one of skill in the art could reasonably predict how to make and use the claimed hybrid maize plants produced from Applicant's exemplified inbred maize plant.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 1-10 are rejected under 35 U.S.C. § 103(a) as being obvious over Boulch et al (U.S. Patent 6,781,042, filed 15 October 2002, with a U.S. priority date of 28 January 2000).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. § 102(e). This rejection under 35 U.S.C. § 103(a) might be overcome by: (1) a showing under 37 CFR § 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR § 1.131; or (3) an oath or declaration under 37 CFR § 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. § 104, together with a terminal disclaimer in accordance with 37 CFR § 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was

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made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2). Boulch *et al* teach inbred maize line PH0GC in Tables 2a and 2b at columns 33 and 34. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to use inbred maize line PH0GC to produce hybrid progeny plants given the teachings of Boulch *et al*, and one of ordinary skill in the art would have had a reasonable expectation of success given the teachings of Boulch *et al*.

Double Patenting

10. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. § 101.

11. Applicant is advised that should claims 2 and 3 be found allowable, claims 5 and 6 will be objected to under 37 CFR § 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The issue of indefiniteness of claims 2 and 3 are addressed supra, but read on their own, claims 2 and 3 appear to encompass the same subject matter as claims 5 and 6.

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Conclusion

- 12. No claims are allowed.
- 13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D. DATERIT FXAMINER

David H. Kruse, Ph.D. 15 February 2005

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.